



AMERICAN FOREST & PAPER ASSOCIATION
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August 16, 2005

Division of Dockets Management (HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, Maryland 20852

**Re: Draft Report of the Threshold Working Group, CFSAN:
Approaches to Establish Thresholds for Major Food
Allergens and for Gluten in Food
FDA Docket No. 2005N-0231
70 Fed. Reg. 35258 (June 17, 2005)**

These comments are submitted by the American Forest & Paper Association (AF&PA), the national trade association of the forest, pulp, paper, paperboard, and wood products industry. AF&PA represents member companies engaged in growing, harvesting, and processing wood and wood fiber; manufacturing pulp, paper, and paperboard products, including food packaging and food contact substances, from both virgin and recycled fiber; and producing engineered and traditional wood products. AF&PA members include manufacturers of over eighty percent of the paper, wood, and forest products produced in the United States.

AF&PA welcomes this opportunity to comment on the Draft Report of the Threshold Working Group. AF&PA appreciates FDA's recognition of the fact that requiring declaration of every *de minimis* amount of an allergen would be contrary to the purposes of the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) and public health goals more broadly. In these comments, AF&PA wishes to make the agency aware of significant, unintended complications relating to food packaging materials and food contact substances.

As discussed more fully below, low levels of food allergen-derived materials are lawfully used in the vast majority of paperboard food packaging. Accordingly, if these substances are not excluded from the FALCPA's labeling requirements, almost every food product in a paperboard package will need to bear allergen labeling, even where the food itself

contains no allergenic ingredients. Such blanket allergen declarations will be virtually meaningless because no allergic reactions attributable to food allergens in packaging or food contact substances have ever been reported. Allergen labeling to declare substances in food packaging would therefore be contrary to the purposes of the FALCPA, and would also undermine a number of significant environmental public policy considerations. Accordingly, AF&PA requests that, in considering its approach to the implementation of FALCPA and the establishment of thresholds for major food allergens and gluten, FDA categorically exclude food packaging and food contact substances from the scope of the food allergen labeling requirements. FDA has the legal authority to establish such an exclusion, and doing so is consistent with and in furtherance of the Congressional intent behind the FALCPA.

I. Extending the FALCPA to Food Packaging and Food Contact Substances Would Unjustifiably Require Allergen Declarations on a Vast Range of Food Products

The use of small amounts of substances derived from one or more of the eight major food allergens – such as soy-derived glues and polymers, wheat-derived starches for glues and coatings, or casein-derived coatings or additives to the paperboard itself – is nearly universal in the manufacture of paperboard food packaging and food contact substances. The use of soy-derived substances in food packaging and food contact substances is well documented in FDA regulations, for the agency has expressly authorized thirty-six soy-derived indirect food additives as safe for such uses.¹ In addition, FDA acknowledges by regulation the safe use of starch,² including wheat starch, and casein³ in paper and paperboard food packaging. In accordance with these regulations, a broad range of paperboard food packages contain low levels of allergen-derived substances.

The presence of allergens in food packaging is particularly complicated by the widespread use of recycled paperboard. Even where allergen-derived substances are not affirmatively used in or applied to a food package, if the paperboard itself is made from recycled material it would be impossible to assure that the packaging contained no substances derived from allergens.

Under the FALCPA, a food label must declare the presence of a major food allergen, whether that allergen is an ingredient in the food or constitutes or is contained in a flavoring, coloring or incidental additive in the food.⁴ A broad reading of that Act could extend its requirements even to food packaging and food contact substances. Under such an interpretation, if no exclusion were made for the *de minimis* amounts of food allergens that could potentially migrate from food packaging and food contact substances into food, virtually all food

¹ See attached list of soy-derived indirect food additives and their authorizing regulations.

² 21 C.F.R. §§ 172.892, 175.105, 176.130, 178.1010, 178.3520, 182.90.

³ 21 C.F.R. § 182.90.

⁴ 21 U.S.C. § 343(w)(4).

packaged in paperboard packaging would need to bear an allergen declaration, due to the widespread use of allergen-derived substances in the packaging.

Such an illogical result was clearly not the intent of Congress in enacting the FALCPA to protect food-allergic consumers and provide information that facilitates food choices by such consumers. Indeed, AF&PA and its members are not aware of even a single incident of an allergic response attributable to the use of allergen-derived substances in food packaging and food contact substances throughout the long history of use of such substances. Accordingly, to require label declaration of *de minimis* levels of allergens contributed by food packaging would serve no public health benefit whatsoever, but rather would contribute to widespread consumer confusion and would undermine the value of meaningful allergen declarations where allergens are or comprise actual ingredients in food.

As a practical matter, it is difficult to conceive of how the imputed presence of an allergen from packaging would be declared on such packages. The FALCPA addresses the ingredient declaration of packaged foods, as that Act is focused upon ingredients intended to become the components of a finished food. The allergen-derived substances in food packaging would not properly be identified in the ingredient declaration itself, as the food is not “fabricated” from allergens in its packaging,⁵ and packaging materials are not what consumers understand to be ingredients in their food. Further, to state after the ingredient declaration that the product “contains” an allergen such as soy, wheat, or milk, where the ingredient declaration itself suggests no soy, wheat, or dairy ingredient would surely invite consumer confusion.

Given the fact that no incidents of allergic reactions attributable to food packaging or food contact substances have ever been reported, such a proliferation of allergen declarations based solely upon the *de minimis* amounts of allergen-derived substances in food packaging would undermine the purposes of FALCPA. Such allergen declarations would provide no meaningful information to allergic consumers and would likely cause them to avoid a broad range of foods that would in fact present no risk to them. Of greater concern is the possibility that such an abundance of allergen declarations, particularly on foods known to pose no risk of harm in their current packaging, would cause even allergic consumers to disregard allergen declarations more broadly. These same concerns have motivated calls for the judicious use of “may contain” allergen statements,⁶ and undergird FDA’s longstanding general policy disfavoring warnings on food labels.⁷

⁵ See 21 U.S.C. § 343(i)(2).

⁶ See the Food Allergen Labeling Guidelines developed by the Food Allergy Issues Alliance and endorsed by FDA, at <http://www.foodallergy.org/Advocacy/advocacy2.html> (advising that supplemental allergen statements should be used judiciously and only when the presence of a major food allergen in food is documented, unavoidable, and potentially hazardous).

⁷ See, e.g., 63 Fed. Reg. 37030, 37035 (July 8, 1998) (unpasteurized juice warning) (FDA agreeing that “too many warning labels on foods could result in loss of consumer credibility and effectiveness.”); 42 Fed. Reg. 22018 (April 29, 1977) (warning for fluorocarbons) (FDA stating (continued...))

Additional environmental public policy considerations favor an exclusion from allergen labeling for food packaging and food contact substances. The first relates to the widespread use of recycled materials in paperboard food packaging, as noted above. Requiring the declaration of food allergens in food packaging and food contact substances could have the negative effect of discouraging many establishments from using packaging containing recycled materials in an attempt to avoid the possible presence of *de minimis* amounts of allergen derived materials.

Second, the development and generalized use of biogenic polymers from renewable resources (rather than from non-renewable resources like petroleum) such as those from soy and starch represent eco-efficient practices that contribute to responsible manufacturing. The use of these biogenic substances should be encouraged rather than disfavored. Unjustifiable regulatory barriers to their use, such as an immaterial allergen labeling requirement, should be eliminated.

Third, requiring allergen labeling for substances in food packaging could have the unfortunate effect of discouraging the use of paperboard packaging generally. Paperboard is ecologically preferable to many other options because it is biodegradable, recyclable, and made from renewable, and often recycled, materials. AF&PA requests that FDA consider these additional public policy factors weighing in favor of an exclusion from FALCPA for paperboard food packaging and food contact substances. As no food allergic reactions have ever been attributable to food packaging, a labeling requirement that would undermine these public policy considerations is wholly unjustified.

While AF&PA recognizes that the FALCPA provides for extensive petition and notification processes to seek exemption from the allergen labeling requirements, these options are simply not viable for the paperboard food packaging and food contact substance industry. Because of the broad range of allergen-derived substances used in a variety of types of packaging, and the complications that arise from the widespread use of recycled materials, a large number of individual petitions or notifications would need to be submitted with respect to each such use of allergen-derived substances, including data on the amount of allergenic protein in each substance and migration from each type of package or food contact substance. The immense burden that would be imposed upon manufacturers of paperboard food packaging and food contact substances is plainly unjustified in the absence of any evidence that these substances have ever been responsible for an allergic reaction in food allergic consumers.

that the Federal Food, Drug and Cosmetic Act (FD&C Act) “authorizes warnings and affirmative disclosures only with respect to serious hazards”).

II. FDA is Authorized to Exempt Food Packaging and Food Contact Substances From FALCPA

There is no indication that Congress intended or even contemplated that food packaging and food contact substances could be deemed within the sweep of FALCPA, for they are not mentioned in the language of the Act itself nor anywhere in its legislative history. Accordingly, excluding food packaging and food contact substances from the Act would not contravene Congressional intent; rather, for the reasons discussed in the preceding section, such an exclusion would further the purposes of the FALCPA by not diluting the value of meaningful allergen labeling.

FDA has authority to exclude food contact substances from the scope of the FALCPA based upon the *de minimis* principle of statutory construction inherent in the FD&C Act. FDA has long relied upon this authority in establishing its food defect action levels for substances that would adulterate food based upon a literal reading of section 402(a)(1) of that Act.⁸ Although 402(a)(1) provides that a food shall be deemed to be adulterated “if it bears or contains *any* poisonous or deleterious substance,”⁹ FDA has established levels below which certain substances are deemed not to be adulterants, because they present no hazard to health.¹⁰ Under this same principle, FDA is authorized to establish categorically that allergen-derived substances in food packaging and food contact substances present no hazard to health and therefore need not be declared on food packaging pursuant to the FALCPA.

The FALCPA itself grants FDA the authority to eliminate, by regulation, the food allergen labeling requirements if necessary to protect the public health.¹¹ For the reasons discussed in the foregoing section, excluding food packaging and food contact substances from the scope of the FALCPA is necessary to protect the public health by preserving the value of meaningful allergen declarations and preventing the widespread consumer confusion that would certainly flow from labeling virtually all paperboard food packages with allergen statements. Accordingly, if FDA believes that the *de minimis* principle inherent in the FD&C Act is insufficient to authorize the agency to exclude food packaging and food contact substances from the FALCPA, then AF&PA requests that FDA promulgate a regulation eliminating the allergen declaration requirements for allergen-derived substances in food packaging and food contact substances.

III. Conclusion

In conclusion, given that the focus of the FALCPA is on ingredients with a given functionality that are intended to become components of a finished food, AF&PA requests that

⁸ 21 U.S.C. § 342(a)(1).

⁹ *Id.* (emphasis added).

¹⁰ See 21 C.F.R. § 110.110.

¹¹ 21 U.S.C. § 343(w)(5).

FDA categorically exclude food packaging and food contact substances from the scope of the FALCPA. The widespread *de minimis* use of allergen-derived substances in food packaging and food contact substances and the fact that no allergic reactions have ever been attributed to these substances are substantive reasons for this exclusion request. Such an exclusion is a) within the present authority of the FDA, b) consistent with the purposes of the FALCPA because it will preserve the value of meaningful allergen declarations and will allow FDA to focus its attention and resources on establishing thresholds for allergen-derived ingredients that are intended to be ingested as components of finished foods, and c) compatible with the environmental public policy considerations favoring the use of recycled, recyclable, and renewable substances comprising paperboard food packaging and food contact substances.

John L. Festa, Ph.D.

A handwritten signature in blue ink that reads "John L. Festa". The signature is fluid and cursive, with the first name "John" and last name "Festa" clearly legible.

Senior Scientist
American Forest & Paper Association

Attachment

8393	SOYAALKYD RESIN	977037-48-1	177.1680
6725	SOYBEAN OIL	008001-22-7	175.300 176.210 178.2800
7590	SOYBEAN OIL, CRUDE	977044-34-0	175.300
7591	SOYBEAN OIL, CRUDE, DEGUMMED	977032-67-9	175.300
7992	SOYBEAN OIL, DIETHYLENE GLYCOL ESTERS	977037-57-2	176.210 177.2800
7993	SOYBEAN OIL DIGLYCERIDES	068553-04-8	176.210
7994	SOYBEAN OIL DIGLYCERIDES, HYDROGENATED	068553-05-9	176.210
3043	SOYBEAN OIL, EPOXIDIZED	008013-07-8	172.723 175.105 175.300 177.1650 178.3910 181.27
6727	SOYBEAN OIL, EPOXIDIZED-TRIMELLITIC ANHYDRIDE COPOLYMER	977147-39-9	177.1210
7592	SOYBEAN OIL FATTY ACIDS	068308-53-2	175.300 176.180 176.210 177.2800
6728	SOYBEAN OIL FATTY ACIDS, ALUMINUM SALT	977114-81-0	175.300
6730	SOYBEAN OIL FATTY ACIDS, CERIUM SALT	008030-94-2	175.300
6731	SOYBEAN OIL FATTY ACIDS, COBALT SALT	977078-18-4	175.300
7593	SOYBEAN OIL FATTY ACIDS, DIMERIZED, POLYGLYCEROL ESTERS	977108-08-9	175.105 175.300
6732	SOYBEAN OIL FATTY ACIDS, IRON SALT	977114-79-6	175.300
6733	SOYBEAN OIL FATTY ACIDS, LITHIUM SALT	977114-80-9	175.300
6734	SOYBEAN OIL FATTY ACIDS, MAGNESIUM SALT	977114-78-5	175.300
6735	SOYBEAN OIL FATTY ACIDS, MANGANESE SALT	977114-77-4	175.300
7996	SOYBEAN OIL FATTY ACIDS, METHYL ESTERS	068919-53-9	176.210 177.2800
7594	SOYBEAN OIL FATTY ACIDS, PEG-8 ESTERS	977164-60-5	175.300 176.180 176.210 177.2800
8394	SOYBEAN OIL FATTY ACIDS, SODIUM SALT	061790-25-8	177.2800
6736	SOYBEAN OIL FATTY ACIDS, ZINC SALT	977114-76-3	175.300
6737	SOYBEAN OIL FATTY ACIDS, ZIRCONIUM SALT	977114-75-2	175.300
7997	SOYBEAN OIL GLYCERIDES, HYDROGENATED	091745-04-9	176.210

			177.2800
2787	SOYBEAN OIL, HYDROGENATED	008016-70-4	176.180 176.210 177.2800 182.70
8395	SOYBEAN OIL, HYDROGENATED, OXIDIZED	977157-96-2	177.2800
7596	SOYBEAN OIL, MALEATED	068648-66-8	175.300
7998	SOYBEAN OIL MONO- AND DIGLYCERIDES, HYDROGENATED	091052-82-3	176.210
7999	SOYBEAN OIL MONOGLYCERIDES	068201-47-8	176.210
8000	SOYBEAN OIL MONOGLYCERIDES, HYDROGENATED	061789-08-0	176.210
7597	SOYBEAN OIL, OXIDIZED	091081-85-5	175.300 176.180 176.210 177.2800
7598	SOYBEAN OIL, PEROXIDIZED	977159-18-4	175.300
7599	SOYBEAN OIL, REFINED	977028-20-8	175.300
8396	SOYBEAN OIL, SULFATED	977037-38-9	177.2800
8397	SOYBEAN OIL, VULCANIZED	008016-71-5	177.2600
2789	SOY PROTEIN		